



JAN 21 1998

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Sherilyn R. Lucas
Administrative Assistant
Nutraceutical Products Company, dba NUPRO
735-L Park Street
Castle Rock, Colorado 80104

Dear Ms. Lucas:

This is in response to your letter of December 16, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Nutraceutical Products Company, dba NUPRO, is making the following statements, among others, for the product OsteofleX GS-12:

“... manage the body’s ability to generate new blood vessels, a factor in the swelling and stiffness associated with over-used or aging joints” (statement 2)
“...helps with muscle discomfort”

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate disease, in that it is intended to treat, prevent, or mitigate degenerative and/or other joint diseases and conditions and to treat muscle or mitigate muscle conditions. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that this product is intended for use as a drug within the meaning of section 201 (g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10,7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritional
Center for Food Safety
and Applied Nutrition

975-0163

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Received
12/30/17

**NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA
AND 21 C.F.R. 5101.93**

This notification is being filed on behalf of **Nutraceutical Products Company**, dba NUPRO which is the marketer of the product(s) which bear the statements identified in this notification. Its business address is: 735-L Park St, Castle Rock, CO 80104. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is **OsteoFlex GS-12**.

The text of each **structure-function statement** for which notification is now being given is:

- (Statement 1) The connective tissue and cartilage in the body includes a natural compound, **Glucosamine**, involved in the formation of nails, tendons, skin, eyes, bones, ligaments and heart valves. Most importantly, it contributes to the strength and integrity of joint structures.
- (Statement 2) Powderized cartilage with calcium, phosphorus, amino acids, mucopolysaccharides and chondroitin sulfate, a helpful agent for managing swelling. Shark Cartilage seems to manage the body's ability to generate new blood vessels, a factor in the swelling and stiffness associated with over-used or aging joints.
- (Statement 3) Called "The Opener of the Way" in **Peru**, **Cat's Claw** supports the bowel, immune system, gastrointestinal tract, digestive system, cardiovascular system and helps with muscle discomfort.
- (Statement 4) Vital in the production and assimilation of **collagen**, an important cellular component of connective tissues, muscles, tendons, bones, teeth and skin. Humans are incapable of synthesizing **Vitamin C** and must rely on dietary sources or supplements for optimal health.
- (Statement 5) The Tumeric rhizome is widely utilized to support joint function.
- (Statement 6) Magnesium, vital to enzyme activity, **assists in calcium** and Potassium uptake, plays a role in the formation of bone and in carbohydrate and mineral metabolism.
- (Statement 7) Required by **all** cells in the body and is concentrated in the organs. Known as the **anti-stress vitamin** it plays a role in the production of adrenal hormones, the formation of antibodies, aids in **vitamin** utilization and helps convert fats, carbohydrates and proteins into energy.
- (Statement 8) In traditional Indian systems (Ayurveda), **Ginger** is used to support the joints and circulatory system.
- (Statement 9) Noted as a flavoring, the multitude of beneficial effects of licorice is attributed to the **presence of glycyrrhizin**. A hydrolyzed compound of **glycyrrhizin (Glycyrrhetic acid)** is used in Europe for its ability to maintain normal fluid levels in joints.
- (Statement 10) Minute quantities of **Manganese** are needed for protein and fat metabolism, healthy nerves, healthy immune system and blood sugar regulation. It is used for energy production and required for bone growth and reproduction.
- (Statement 11) Needed for proper circulation and **healthy skin**, aids in the functioning of the nervous system in the metabolism of carbohydrates, fats and proteins.
- (Statement 12) Trace amounts of **Boron** are needed for calcium uptake and healthy bones.
- (Statement 13) Cartilage and connective tissue in the body include a natural compound, **Glucosamine**, contributing to the strength and integrity of joint structures. **OsteoFlex GS-12** is a unique combination of 12 natural ingredients, formulated to nourish cartilage, joints and skeletal structures.

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The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

Statement number	Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement
1.	Glucosamine Sulfate
2.	Shark Cartilage Concentrate:
3.	Cat's Claw (<i>Uncaria Tomentosa</i>):
4.	Vitamin C:
5.	Curcumin (Turmeric 50: 1):
6.	Magnesium Sulfate:
7.	Pantothenic Acid (vitamin B ₅):
8.	Ginger (root):
9.	Licorice (root):
10.	Manganese Sulfate:
11.	Niacinamide (Vitamin B ₃):
12.	Boron Citrate
13.	OsteoFlexGS- 12 Formula

The following identifies the brand name of each supplement for which a statement is made:

Statement Number	Brand Name	Label or Labeling
1 - 13	OsteoFlexCGS- 12	NUPRO

I, Sherilyn R. Lucas, am authorized to **certify** this Notification on behalf of Nutraceutical Products Company, dba NUPRO. I certify that the information presented and contained in this Notification is complete and accurate, and that Nutraceutical Products Company, dba NUPRO has substantiation that each structure-function statement is **truthful** and not misleading,

Date Signed: December, 16, 1997

By: Sherilyn R. Lucas
Sherilyn R. Lucas
Administrative Assistant